

Statement

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I, Prof. Dr. med. Werner Lang, do hereby declare:

1. I am a citizen of Germany.
2. I am a professor („Apl. Prof.“) at Friedrich-Alexander-Universität Erlangen-Nürnberg.
3. I am a vascular surgeon and phlebologist.
4. I was appointed by the Bundesgerichtshof („BGH“), the Federal Supreme Court of Germany, as the expert to advise the court in proceedings related to the German patent DE 694 18 286 T2, corresponding to European patent EP 656 203 B1.
5. This statement is a summary of my opinion regarding air-based sclerosant foams, as expressed to the BGH during the oral hearing of 22 May 2007.
6. It is common practice to treat varicose veins by injecting a sclerosant foam into the venous system e.g. into the greater saphenous vein. The sclerosant foam is almost always made by combining air and a sclerosing chemical such as polidocanol.
7. It is my opinion that complications for the patient from the injection of air or nitrogen into the venous system during this procedure are minimal. It is also my opinion that there is little risk of air embolism by injection of air or nitrogen unless larger volumes are involved.
8. It is my opinion that the adverse events which have been reported in the literature (stroke, migraine, visual disturbance, chest pain) resulting from the injection of an air or nitrogen sclerosant foam into the venous system for the treatment of varicose veins can be mostly avoided by

controlling the amount of foam and/or the veins which are exposed to the sclerosant foam.

9. It is also my opinion that the cerebral events mentioned in paragraph 8 (migraine, visual disturbance, stroke) have been caused by the sclerosant chemical (e.g. polidocanol) reaching the cerebral vasculature (and probably resulting in cerebral vasospasm) rather than by any gas which may have reached the cerebral vasculature.
10. I am only aware of the use of air as the gas in sclerosant foams prior to 1993. However, if there were a problem with the use of air or nitrogen sclerosant foams and a clinician were asked what gas he or she would use as a replacement for the air or nitrogen, the logical choice would be carbon dioxide.
11. In my opinion, there are several reasons why carbon dioxide is the logical choice: (1) carbon dioxide is the only gas supported by the literature as being safe for injection into the venous system, (2) it is commonly injected into the arterial or venous system by clinicians as an angiographic contrast agent, (3) it is significantly more soluble in blood than any other gas commonly available, and (4) it is widely available to clinicians and inexpensive.
12. In my opinion, oxygen or a mixture of oxygen and carbon dioxide would not be used in view of the widespread availability and acceptance of carbon dioxide for intravenous use. Oxygen is not accepted by the medical community for injection. It is viewed by clinicians solely as a gas for inhalation.



Prof. Dr. med. Werner Lang

23 October 2007

Date